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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/04	A1	(11) International Publication Number: WO 98/31286
		(43) International Publication Date: 23 July 1998 (23.07.98)

(21) International Application Number: PCT/US98/01102

(22) International Filing Date: 21 January 1998 (21.01.98)

(30) Priority Data:

60/035,883	21 January 1997 (21.01.97)	US
Not furnished	20 January 1998 (20.01.98)	US

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

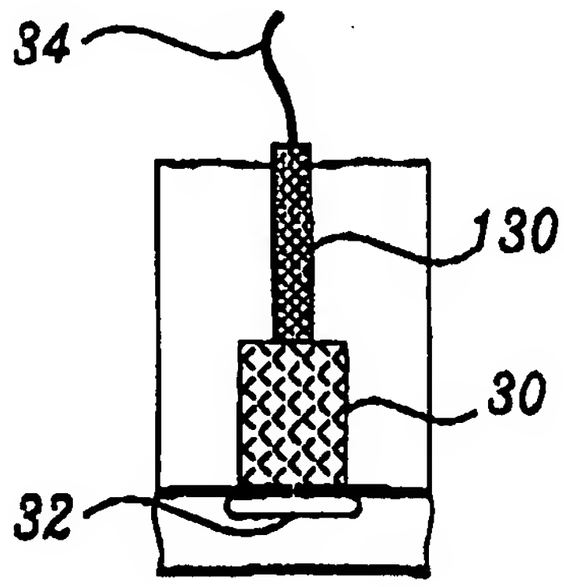
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: HEMOSTASIS PROMOTING DEVICE FOR SEALING A PUNCTURE IN A PATIENT

(57) Abstract

A hemostasis promoting device (20) is disclosed for sealing a puncture or puncture (24) in the body of a patient wherein the closure device (22) includes an anchor member (32), a collagen plug (30), a filament and a bioabsorbable tamping member (130) wherein the tamping member includes a clot promoting agent therein to prevent capillary bleeding in the proximal portion of the puncture and to eliminate blood seepage past the collagen plug to ensure that the patient may be promptly and reliably ambulated within a relatively short period of time once the closure device has been administered to the patient.



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HEMOSTASIS PROMOTING DEVICE FOR SEALING A PUNCTURE IN A PATIENT

FIELD OF THE INVENTION

The present invention relates generally to a device to seal openings in the body of a patient and, more particularly, to an improved hemostatic puncture closure device which preferably includes an anchor, collagen member and a bioabsorbable tamping member.

BACKGROUND OF THE INVENTION

In United States Letters Patent No. 5,021,059; U.S. Patent No. 5,222,974 and U.S. Patent No. 5,282,827 granted to Kensey et al. there is disclosed a closure device and method of use for sealing a small incision or puncture in tissue separating one portion of the body of a living being from another portion thereof; e.g., a percutaneous puncture in an artery, to prevent the flow of a body fluid; e.g., blood, through the puncture. The closure device is arranged to be used with and deployed by an instrument which comprises a carrier or delivery instrument in the form of a tubular member. The tubular member has a proximally located portion and a distally located portion. The latter includes an open free end which is arranged to be introduced through the incision or puncture. The proximately located portion of the tubular member is arranged to be located externally of the body of the human patient when the distally located portion is extended through the incision or puncture.

The closure device of the Kensey patents are generally comprised of three basic components; namely, an anchor member, a sealing member and a filament; e.g., suture. The

sealing member is formed of a hemostatic material; e.g., compressed collagen foam. The anchor member includes a tissue engaging portion configured to pass through the puncture in one direction but resistant to passage therethrough in the opposite direction. The sealing member includes a tissue engaging portion. The filament is connected between the anchor member and the sealing member in a pulley-like arrangement so that they may be moved relative to each other by the application of a pulling force on the filament.

The delivery instrument is arranged to expel the anchor member through the puncture; e.g., into the artery, and to draw the tissue engaging portion of the anchor member into engagement with the tissue contiguous with the puncture. The filament extends through the instrument to a point outside the body of the patient and is arranged to be drawn in the proximal direction, whereupon the portion of the filament connecting the anchor member and the sealing member causes the tissue engaging portion of the sealing member to move with respect to the anchor member and into engagement with the tissue contiguous with the puncture on the opposite side thereof from the anchor member. This action causes the tissue engaging portion of the sealing member to seal the puncture from the flow of fluid therethrough. In an alternate embodiment disclosed in U.S. Patent No. 5,282,827 there is a disclosure of using a bioabsorbable tamping member formed of the same material as is used in the sealing portion or plug of the closure.

The closure device and deploying instrument disclosed in Patent Nos. 5,021,059; 5,222,974 and 5,282,827 occasionally leave something to be desired from the standpoints of effectiveness and efficiency of use. For example, during clinical use of a device of this type, it has been found that in occasional patients that, although the bleeding from the blood vessel has been stopped, bleeding may occur in the puncture tract to cause a small

amount of blood to be present along the skin of the patient adjacent to the puncture. Additionally, it has been found to be desirable to have closure devices capable of closing punctures of various sizes and allowing rapid ambulation of the patient. With currently available closure devices it is necessary to have the patient remain immobile for a limited amount of time after insertion of the closure device prior to ambulation.

SUMMARY OF THE INVENTION

Accordingly, it is a general object of this invention to provide a device and methods of use which overcome the disadvantages of the prior art.

It is a further object of this invention to provide a system including a closure, a deploying instrument and method of use for quickly, easily, safely and effectively sealing a percutaneous puncture in a blood vessel within the body of a living being.

It is another object of this invention to provide devices and methods for enabling one to promptly stop bleeding from the tissue surrounding a percutaneous incision or puncture once the incision through the blood vessel wall has been sealed.

It is yet another object of the present invention to provide a system which may be used for sealing punctures of various sizes without having to either enlarge the puncture or use a different device for each size of puncture.

These and other objects of this invention are achieved by providing a system for sealing a percutaneous incision or puncture in a blood vessel of a human patient. The system generally includes a carrier device, an introducer member and a closure assembly. The puncture comprises a tract extending through tissue overlying a target organ such as a blood vessel. The closure assembly generally

includes an anchoring member, a first sealing member and a filament member as well as an additional bioabsorbable member which is referred to hereinafter as the tamping member. The filament member is connected between the anchoring member and the first sealing member. The introducer member consists of a tubular member having a distal free end arranged to be inserted into the puncture tract and through the puncture. The carrier member is arranged to be inserted through the introducer member to expel the anchoring member therefrom and to draw the anchoring member into engagement with the distal free end of the introducer member. The introducer member and the carrier member are arranged to be moved together to draw the anchoring member into engagement with the interior tissue of the blood vessel generally adjacent to the puncture. The filament member is arranged to pull the anchoring member and the first sealing member relative to each other to cause the sealing member to engage tissue contiguous with the puncture along the outside of the blood vessel.

In accordance with one aspect of this invention the system includes the bioabsorbable tamping member and a method of use to enable one to readily stop incidental bleeding from the puncture tract once the wall of the blood vessel or lumen has been sealed. In accordance with another aspect of the present invention, the filament member, anchoring member and first sealing member may be used to seal incisions or punctures of various sizes, and the size and clot promoting ingredients of the tamping member may be varied to accommodate different sizes of punctures or incisions.

In accordance with another aspect of this invention the system includes the bioabsorbable tamping member and a proximally positioned locking disk. This embodiment also includes a method of use to enable one to readily stop incidental bleeding from the puncture tract once the wall

of the blood vessel or lumen has been sealed. In accordance with another aspect of this embodiment of the present invention, the filament member, anchoring member and first sealing member may be used to seal incisions or punctures of various sizes, and the size and clot promoting ingredients of the tamping member may be varied to accommodate different sizes of punctures or incisions while the proximally positioned locking disk securely holds each of the components in their desired position in the puncture.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and many of the attendant advantages of this invention will readily be appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Figure 1 is a side elevational view, partially in cross section, showing the deployment instrument and closure device of the present invention;

Figure 2 is a side elevational view showing the components of the sealing device of the present invention;

Figure 3 is a side elevational view of the tamping member of the present invention;

Figure 4 is a side elevational view showing the insertion of the deployment instrument and closure device into the introducer sheath which has been previously positioned in the blood vessel and puncture tract of the patient;

Figure 5 is a side elevational view showing the insertion of the anchor member of the closure device into the blood vessel of the patient;

Figures 6A and 6B are side elevational views showing the positioning of the anchor member adjacent to the distal end of the introducer sheath;

Figure 7 is a side elevational view showing the withdrawal of the introducer sheath and deployment instrument from the puncture to position the anchor member adjacent to the wall of the blood vessel of the patient;

Figure 8 is a side elevational view showing the release of the sealing member from the deployment instrument as the introducer sheath and deployment instrument are withdrawn from the puncture;

Figure 9 is a side elevational view showing the release of the tamping member from the deployment instrument as the introducer sheath and deployment instrument are withdrawn from the puncture;

Figure 10 is a side elevational view showing the release of the tag on the positioning member from the deployment instrument as the introducer sheath and deployment instrument are withdrawn from the puncture;

Figure 11 is a side elevational view showing the positioning of the torsion spring on the positioning member to apply pressure to the tamping member;

Figure 12 is a side elevational view showing the positioning of the closure device of the present invention in the puncture and blood vessel of the patient;

Figure 13 is a side elevational view, partially in cross section, showing the deployment instrument and an alternate form of the closure device of the present invention;

Figure 14 is a side elevational view of an alternate form of the components of the sealing device of the present invention;

Figure 15 is a side elevational view showing the positioning of the closure device of Figure 12 in the puncture and blood vessel of the patient;

Figure 16 is an enlarged side view of the locking disk of the embodiment of Figure 12; and

Figure 17 is an enlarged top view of the locking disk of the embodiment of Figure 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 an instrument forming a portion of a system for deploying a closure device 22 to seal a percutaneous puncture 24 within a blood vessel 26; e.g., the femoral artery, constructed in accordance with this invention. The percutaneous puncture 24 includes not only the opening in the wall of the vessel but also the tract 24; i.e., the passageway in the tissue located between the vessel and the skin of the human being formed when the vessel is punctured. As used herein, the distal end of an element is referred to as the end of the element nearest to the patient and the proximal end of an element is referred to as the element furthest from the patient.

The preferred form of the instrument 20 and closure device 22 have particular utility when used in connection with intravascular procedures, such as angiographic dye injection, cardiac catheterization, balloon angioplasty, stents and other types of recanalizing of atherosclerotic arteries, etc. since the closure device 22 is designed to cause immediate hemostasis of the blood vessel; e.g., arterial, puncture. However, it is to be understood that while the description of the preferred embodiment instrument and closure device contained herein is directed to the closure of percutaneous incisions or punctures in arteries, the present invention is believed to have much more wide-spread application. Thus, the sealing of a

percutaneous opening in an artery shown herein is merely exemplary.

Before describing the closure 22 and the instrument 20 for inserting it to seal the opening, a brief description of a typical, conventional, intravascular surgical procedure; e.g., catheter instrumentation of an artery, utilizing a percutaneous opening will be given to best appreciate the features of the invention. In such a procedure a cannula of an instrument, such as an angiographic needle (not shown), is inserted percutaneously through the skin into the artery, such as the femoral artery, at the situs for the instrument's insertion. The needle cannula is held in place, and the flexible end of a guidewire (not shown) is then passed through the cannula into the artery to the desired depth (i.e., longitudinal position therealong). Once the guidewire is in place, the needle cannula is removed, leaving the guidewire in place. An introducer sheath 28 and an arterial dilator (not shown) are then passed over the guidewire, through the puncture or incision and into the artery. The guidewire and then the dilator are removed leaving the introducer sheath in place. A catheter, or other intravascular instrument (not shown) is then inserted through the introducer sheath 28 and threaded down the artery 26 to the desired intravascular location; e.g., the situs of the atherosclerotic occlusion.

Once the intravascular procedure (e.g., angiography, angioplasty or stent placement) has been completed, the catheter is removed. Thereafter, the sheath is removed and the surgeon or other trained person previously applied manual, digital pressure to the percutaneous puncture until hemostasis has occurred. In particular, the current standard of care for puncture hemostasis is to apply digital or mechanical pressure on the puncture site for twenty minutes to an hour, depending on the puncture size and the degree of hemolytic therapy. Obviously, this results in wasted time for the physicians and other

hospital personnel and causes inconvenience and discomfort for the patient. In addition, serious complications may arise from persistent bleeding and hematoma formation in approximately five percent of the patients.

In accordance with the method of this invention, the introducer sheath 28 is left in place within the artery following the intravascular procedure (although it is moved so that its distal end is at a desired position therein, as will be described later). The deployment instrument 20 having the closure device 22 therein is inserted into the introducer sheath. The closure device is then deployed (ejected) and operated to immediately seal the percutaneous puncture including the arterial wall and the tract 24. Moreover, as will be appreciated from the description to follow, the closure device 22 is designed to reduce post-procedure puncture complications, cause minimal inflammatory reaction and resorb completely within a relatively short period of time.

The details of the closure 22 and instrument 20 for introducing it are described in detail below. Suffice it for now to briefly describe the preferred embodiments of the closure and their method of deployment and use. Thus, as will be described in detail below, the closure has three conventional sealing components; namely, a sealing member 30, an intraarterial anchor member 32, and a positioning member 34. In the present invention, the closure 22 also includes an additional porous tamping member 130 and preferably a locking disk 152 (in the alternate embodiment of the present invention), both of which are described in more detail below. The sealing member is in the form of an elongated rod-like plug; e.g., a hemostatic, resorbable collagen sponge or foam. This member is arranged for sealing the puncture. The anchor member 32 is an elongated, stiff, low-profile, resorbable member which is arranged to be seated inside the artery against the artery wall contiguous with the percutaneous puncture 24. The

anchor member 32 is made of non-hemostatic resorbable polymer similar to resorbable suture or other moldable material such as a lactide and/or glycolide polymer. The anchor member 32 is preferably non-hemostatic and is sized to be hemodynamically insignificant in comparison to the size of the femoral artery. Thus, the resorbable anchor has an insignificant hemodynamic effect on blood flow. The positioning member 34 comprises a filament; e.g., a resorbable suture. The suture connects the anchor member and the collagen plug (sealing member) via a pulley-like arrangement which serves to move the anchor and plug together, to sandwich and lock the artery wall between the anchor and plug. The tamping member 130 is preferably an elongate and cylindrical bioabsorbable member which has a greater columnar strength than the sealing member 30. The locking disk 152 is preferably a circular member that is formed of a material which is similar to that of the anchor member 32 and which is designed to engage the positioning member 34 proximally of the sealing member 30 and tamping member 130.

The sealing member 30 is preferably formed as a collagen plug which comprises a hemostasis promoting cylindrical member formed of a compressible, resorbable, collagen foam, such as that sold by Colla-Tec, Inc. of Plainsboro, New Jersey. The sealing member 30 is arranged to be compressed from a larger diameter configuration to a smaller diameter, elongated configuration which is inserted into the introducer sheath 28. In the configuration wherein the sealing member is compressed and inserted into the introducer sheath 28, the diameter of the plug is very small; e.g., about 1.32 mm and, therefore, suitable for disposition within the instrument 20 as will be described later. The sealing member 30 may include an annular recess (not shown) extending about its outer periphery adjacent its proximal end as well as a plurality of apertures (not shown) which may extend through the plug. In particular,

an aperture may be located close to the recess and diametrically through the centerline of the sealing member 30. These apertures serve as passageways through which the positioning member 34 extends to connect the anchor member 32 to the sealing member 30 and are spaced apart to preclude tearing of the sealing member.

The positioning member 34 of the closure device 22 is preferably a suture or other bioabsorbable filament which serves to couple the sealing member 30 to the anchor member 32 in an arrangement to effect the movement of the sealing member 30 toward the anchor member 32, once the anchor member 32 is in its desired position in the artery near the puncture or incision. In particular, the coupling of the sealing member 30 to the anchor member 32 preferably simulates a pulley to achieve a desired mechanical advantage. The tamping member 130 and locking disk 152 are arranged to be slidable distally along the positioning member 34 into their desired position in the puncture tract 24. In accordance with a preferred embodiment of this invention, the positioning member 34 is a filament which is formed of resorbable, flexible, strong material; e.g., a resorbable suture.

The anchor member 32 basically comprises a thin, narrow strip or bar of a preferably moldable material such as a resorbable lactide/glycolide polymer sold by Medisorb Technologies International L.P. under the trade designation MEDISORB. The strip is sufficiently rigid such that once it is in position with the artery (as will be described later) it is resistant to deformation to preclude it from bending to pass back through the puncture through which it was first introduced. The member 32 has a generally planar top surface, a generally planar bottom surface and a peripheral side surface. Each end of the anchor member 32 is preferably rounded. A hemispherical projection is preferably located along the center of the top surface. The hemispherical projection includes a longitudinally

extending slot disposed perpendicularly to the top surface of the anchor member 32. The bottom surface of the slot is preferably arcuate. A cylindrical opening extends transversely across the anchor member 32 through the projection. A loop of suture material extends through the opening. The loop is closed by a knot which is preferably formed proximally of the sealing member. The portion of the loop extending through the opening overlies the bottom of the slot and forms a "pin" about which the positioning member 34 extends. In particular, the positioning member 34 is threaded through the slot and back out of the slot on the other side thereof to connect the sealing member 30 to the anchor member 32.

In this regard the pulley-like connection between the anchor member 32 and the sealing member 30 is effected by threading the positioning member 34 from a remote point (which is located outside the deployment instrument 20 when the closure device is in place in that instrument) through one or more apertures in sealing member 30, down the sealing member to the anchor member 32 where it is threaded through the slot of the anchor member 32 and back to the sealing member where it enters into another aperture and passes through the aperture to the opposite side of the sealing member, where it terminates in a knot.

As can be seen in the drawings, the instrument basically comprises a carrier 100 which includes an elongated tube 102 formed of a somewhat flexible material, such as polyethylene or polyvinyl chloride, so that the carrier may be freely passed through the introducer sheath 28 into an operative position within the patient's artery, notwithstanding any curvature of the introducer sleeve which may exist.

In accordance with a preferred embodiment of this invention, the outside diameter of the tubular carrier 100 is approximately 8-French to correspond to the size of the procedure sheath used in most intravascular procedures.

The distal end of the tube portion of the carrier 100 may include a rigid; e.g., stainless steel sleeve or bypass tube 104 mounted thereon to enable the tubular carrier 100 to be inserted through a conventional hemostasis valve (not shown) forming a portion of the introducer sheath 28, through the sheath and out the distal end thereof into the artery 26. The distal end of the flexible tube 102 preferably necks down into a generally hemicylindrical configuration and may include a longitudinally extending slit (not shown) therein to enable it to be fit within the bypass tube 104 without buckling.

The closure device 22 is preferably initially located within the distal end of the tubular carrier 100. In particular, the anchor member 32 is disposed longitudinally within the bypass tube 104 laterally of the central longitudinal axis 106 of the carrier. The sealing member 30 is located within the tube 102 just behind (proximally) of the anchor member and on the opposite side of the central longitudinal axis. In fact, the distal end of the sealing member preferably overlies the proximal end of the anchor member. The tamping member 130 is positioned proximally of the sealing member 30 in the tubular carrier 100. The bypass tube 104 may also include a reference detent 108 in its periphery located diametrically opposite to the position of the anchor member. The detent 108 serves as a visual guide to help the user orient the instrument to a proper yaw angle with respect to the central longitudinal axis for insertion within the introducer sheath as will be described later.

The proximal end of the instrument 20 preferably includes a conventional luer fitting 110. The proximal end of the carrier tube 102 extends into an opening in the fitting 110 and is secured in place therein by any suitable means. The proximal end of the instrument preferably also includes a hollow body 112 through which the proximal end of the positioning member 34 extends. A tensioning

assembly is located within that body 112 and preferably comprises a ball, a cup-shaped ball seat, a compression spring and a spring seat or a tensioning disk (not shown) although other forms of tensioning devices may be used. As will be appreciated by those skilled in the art, the tensioning assembly just described will tend to hold the filament of the positioning member 34 in place with respect thereto until the force applied to the filament exceeds the preload force applied by the compression spring, whereupon the filament will slide steadily through the instrument 20.

The carrier 100 of this embodiment also includes the tamping member 130 therein. This member is preferably an elongated rod-like cylindrical member formed of any suitable bioabsorbable and clot promoting material; e.g., styptic, porous or polymeric material containing an additional clot promoting material, and is disposed within the carrier tube 102 immediately proximally of the sealing member 30. The tamping member 130 of the present invention is preferably formed of a material which is different than that of the sealing member 30 and has greater rigidity and/or columnar strength as well as greater clot promoting properties than the sealing member 30. The tamping member 130 includes a central passageway 132 extending through its lengthwise dimension from its distal end 134 to its proximal end 136. The tamping member 130 is designed to have sufficient rigidity to allow the user to tamp the collagen or similar material of the sealing member 30 as described below. The tamping member 130 preferably also has sufficient porosity so that, as the tamping member 130 absorbs fluids from the tract of the puncture, the passageway 132 surrounding the positioning member will enclose and engage the positioning member 34 to frictionally retain the anchor member 32, sealing member 30 and tamping member 130 in the tamped position in the puncture. A portion of the positioning member 34 extends from the anchor member 32 through the passageway 132 in the

tamping member 130 and into the hollow body 112 and tensioning assembly.

The positioning of the introducer sheath 28 in the artery may be accomplished utilizing an artery locator device or an obturator in a conventional manner. After the introducer sheath is positioned in the artery, a stopcock may be opened to observe the flow of blood therefrom (thereby indicating that the inlet port or window is within the artery). The introducer sheath is then retracted (moved proximally) until the blood flow through the stopcock just stops, thereby indicating that the distal end of the introducer sheath has just left the artery lumen. The introducer sheath with the device therein is then reinserted approximately 10 mm into the puncture to ensure that the distal end of the introducer sheath is at the desired position within the artery. Blood flow should be reestablished through the stopcock at this time. Then the stopcock is closed. From this point the introducer sheath must be kept fixed (as described earlier), and the deployment instrument 20 carrying the closure device 22 is inserted through the central passageway in the introducer sheath.

As mentioned above, the closure device 22 is used after the interventional procedure is completed. In particular, the physician inserts the delivery or deployment instrument 20 containing the closure device 22 into the previously inserted introducer sheath 28. On insertion of the deployment instrument 20 and closure device 22 through the introducer sheath 28, the anchor member 32 passes out of the distal end of the introducer sheath and deploys into the artery lumen. The deployment instrument 20 and closure device 22 are then withdrawn from the introducer sheath until resistance is felt when the anchor member catches on the distal end of the introducer sheath. Once this occurs (and assuming that the anchor is in the correct orientation when it catches on the end of

the introducer sheath, as will be described later), the deployment instrument and the introducer sheath are then immediately withdrawn together. This withdrawing action causes the anchor member 32 to engage (catch) on the artery wall contiguous with the puncture. Continued withdrawal of the instrument and introducer sheath causes the pulley-like configuration of the positioning member 34 to pull the sealing member 30 toward the anchor member 32, thereby depositing the sealing member 30 in the puncture tract 24 against the exterior of the artery contiguous with the puncture. The pulling on the positioning member 34 to bring the sealing member into engagement with the puncture site also has the effect of deforming the sealing member into a larger diameter body having a reduced length to aid in holding the plug in place to sandwich the wall of the blood vessel between the anchor member 32 and the sealing member 30. Moreover, since the sealing member 30 is formed of a compressible material such as collagen, it also expands automatically in the presence of blood or other fluids within the puncture tract when deployed, thereby further contributing to the closure device's enlargement and sealing capabilities. The instrument 20 also contains the bioabsorbable tamping member 130 which is mounted on the positioning member and which is slidable thereon. The deployment of the sealing member also effects the deployment of the tamping member 130 into the puncture tract proximally of the sealing member. The tamping member is then used to gently compress and position the sealing member 30 along the outside of the artery.

The closure is now initially locked in position in the tract through the clotting of the hemostatic sealing member and by tension on the positioning member 34 attached to the sealing member 30 and the intra-arterial anchor 32. The closure device 22 is further locked in position in the tract by the distal movement of the tamping member 130 in the tract. Thus the artery wall is sandwiched between the

sealing member 30 and the anchor member 32. Within a few hours after deployment, the anchor member 32 will be coated with fibrin and thus attached firmly to the arterial wall, thereby eliminating the possibility of distal embolization. After approximately thirty days, only a small deposit of anchor material will remain. In fact, resorption of all components will have occurred after approximately sixty days.

The insertion and deployment of the closure device through the introducer sheath and into the puncture will now be described in further detail with reference to drawings and is as follows. The reference detent 108 on the bypass tube 104 of the carrier 100 is initially identified by the user. The bypass tube 104 is then grasped by the user and oriented so that the detent faces up (away from the patient). This ensures that the anchor member in the carrier 100 is oriented in alignment with the flow of blood in the blood vessel of the patient. The bypass tube is then inserted into the sheath 28 through the hemostasis valve. The rigid nature of the bypass tube 104 facilitates the passage of the carrier 100 through the hemostasis valve of the sheath and also protects the closure device 22 from damage. The deployment instrument is then pushed fully down the introducer sheath until a stop surface on the front (distal) luer fitting engages the body of the introducer sheath housing the hemostasis valve. At this time the distal end of the carrier will extend through the puncture and will be located in the artery of the patient. The anchor member 32 will also be located in the blood vessel 26 beyond the distal end of the introducer sheath. The bypass tube 104 remains within the proximal portion of the introducer sheath housing the hemostasis valve.

A position indicator clip 29 may then be mounted onto an annular recess on the introducer sheath 28 as shown in the drawings. The clip 29 preferably includes a linear

section from which a yoke projects generally perpendicularly. The yoke may include a circular mouth for receipt of an annular recess on the introducer sheath. When mounted in place on the introducer sheath, the free proximal end of the indicator clip will extend beyond the distal end of the instrument 20 (beyond the tensioner assembly).

The instrument 20 having the closure device therein and the introducer sheath are then operated to determine if the anchor member 32 has been properly deployed. To that end, the introducer sheath is held by the user to prevent axial movement, and the instrument 20 is carefully withdrawn from the introducer sheath. This action causes the anchor member 32 to engage or catch onto the distal end of the introducer. As the anchor member catches on the distal end of the introducer, resistance will be felt by the user. This resistance must be noted by the time the hollow body 112 housing the tensioner assembly reaches the free end of the indicator clip 29. If so, then the anchor member will have caught on the distal end of the introducer at the location of its hemispherical projection (the desired occurrence).

If, however, no resistance is noted by the time that the hollow body 112 passes (extends proximally of) the free end of the indicator clip, this will indicate that the anchor has re-entered the introducer sheath and that the anchor will not catch onto the artery as required. Thus, if no resistance is felt at this point, the instrument 20 must be reinserted within the introducer sheath and the foregoing procedure retried, this time by turning the instrument 20 about its axis by one-quarter turns to each side before it is again withdrawn.

If the resistance is felt before the hollow body 112 reaches the free end of the indicator clip, this will indicate that one of the ends of the anchor member may have caught on the free end of the introducer sheath, an

undesirable occurrence. Accordingly, the instrument 20 must be withdrawn then reinserted within the introducer sheath and the foregoing procedure retried, this time by turning the instrument 20 about its axis by one-quarter turns to each side before it is again withdrawn.

Once the anchor member has been properly deployed from the instrument 20, the sealing member 30 is deployed from the introducer sheath and the instrument into the puncture. To accomplish this, the introducer sheath 28 and the instrument 20 are held together and withdrawn as a unit from the puncture, whilst swinging the unit toward the vertical. This action causes the anchor member 32 to engage or catch onto the inner surface of the artery 26 contiguous with the puncture tract 24. The introducer sheath and the instrument are then pulled further proximally or outward from the puncture. Inasmuch as the anchor member 32 is in engagement with the interior of the artery wall, the continued retraction of the introducer sheath and instrument causes the positioning member 34 to pull the sealing member 30 out of the carrier tube 102 and into the puncture tract 24. As the introducer and instrument come out of the puncture tract, continuous steady resistance will be felt as the previously described tensioner assembly controls the force on the positioning member 34 during the retraction procedure. Continued retraction of the introducer and the instrument brings the tamping member 130 out of the free end of the instrument.

Moreover, the pulley arrangement of the positioning member 34 connecting the anchor member 32 and the sealing member 30 ensures that, during the retraction of the introducer and the deployment instrument, the sealing member 30 is moved towards and preferably into engagement with the exterior of the artery wall contiguous with the puncture 24. In fact, the continued retraction causes the positioning member to somewhat deform the sealing member 30; i.e., cause it to deform radially outward and reduce

the longitudinal length. The existence of blood within the puncture tract further contributes to the deformation of the sealing member since the collagen-like material expands and softens in the presence of blood.

The retraction procedure is continued by pulling the introducer sheath and deployment instrument up the positioning member until a tag 138 is exposed. The tag 138 ensures that the tamping member 130 is withdrawn from the free end of the instrument. At this point the anchor member 32, sealing member 30 and tamping member 130 have been deployed. The sealing member is then tamped by moving the tamping member 130 distally along the positioning member. In particular, the user longitudinally compacts the collagen of the sealing member by pulling on the introducer sheath and deployment instrument in the proximal direction with one hand to gently tension the positioning member while manually sliding the tamping member 130 down the positioning member with the user's other hand so that the tamping member 130 enters the puncture tract 24 and engages the proximal end of the sealing member 30. A few gentle compactions are adequate to achieve the desired result; i.e., to assist the sealing member 30 to conform to the proximal surface of the artery contiguous with the puncture and to assist in locking the sealing member 30 in place until hemostasis occurs (which happens very quickly). It should be noted that during the tamping action care must be taken to maintain tension on the positioning member 34 at a load greater than that used on the tamping member 130 to ensure that the tamping action doesn't propel the sealing member 30 into the interior of the artery.

After the tamping action is completed, a torsion spring 142 may be temporarily mounted on the positioning member 34. This action maintains appropriate tension on the positioning member while the instrument 20 is removed and the positioning member is severed proximally of the tag 138. The spring 142 preferably includes a pair of legs

projecting outward from a helical central section. Each leg includes a slot at its free end. One of the slots is arranged to receive the positioning member 34 therein and to engage the tag 138. The other of the slots is arranged to receive the positioning member 34 therein and to engage the proximal end of the tamping member 130. The legs are biased by the intermediate section so that when the spring is mounted on the positioning member, as just described, they will push the tamping member 130 distally towards the sealing member 30 to hold it in place so that the positioning member can be severed to separate the instrument and the introducer from the closure device. Thus, once the spring is in place, the positioning member on the proximal side of the tag 138 is cut, and the spring applies a light controlled pressure to the sealing member 30 and anchor member 32. The closure device 22 is left in this condition without being disturbed for a few minutes. After that time the spring 142 is removed, and the positioning member is then severed at the top of the tamping member 130. The tamping member 130 is then cut at skin level, and the remaining portion of the filament is taped to the skin surface. The tamping member 130 preferably includes a clot promoting agent therein to prevent bleeding in the puncture due to capillary bleeding or bleeding due to initial blood seepage around the sealing member in the puncture. The length of the tamping member 130 is also chosen so that the tamping member 130 extends proximally in the puncture from the compacted sealing member and preferably at least to the skin level of the patient. Because the tamping member is separated from the flow of blood through the artery by the sealing member, a higher amount of coagulants may be used on the tamping member 130 than is used or is safely available to be used on the sealing member. Additionally, the tamping member 130 may also include a radiopaque material therein to allow the location of the closure device to be

visualized radiographically after the skin surface has healed. This is particularly useful in situations where the patient must undergo another procedure a few weeks after the original procedure is performed so that the physician may observe the location of the prior device and perform the subsequent puncture at a location which is preferably above the prior puncture location. Because the tamping member is preferably formed of a porous and bioabsorbable material, the tamping member 130 may be designed to rapidly soften either due to the absorption of fluids or due to the heat of the patient's body. The ability to use materials which are different from the materials of the sealing member enables the tamping member 130 to quickly and frictionally engage the filament to ensure that the sealing member and anchor member remain in their desired positions relative to the puncture during the initial ambulation of the patient. Additionally, the existence of the clotting agent in the tamping member promotes the rapid discontinuance of bleeding from the puncture by causing any blood which contacts the tamping member to form a clot in the proximal portion of the puncture while the slower acting sealing member and anchor member initially obstruct and then cause complete and final hemostasis in the distal portion of the puncture adjacent to the wall of the blood vessel. The clotting agent in the tamping member also promotes the clotting of any capillary bleeding which may arise as a result of the formation of the puncture tract and/or the passage of the anchor member and sealing member therethrough.

With the closure in final position, the anchor member 32 does not take up a substantial portion of the interior of the artery and, thus, does not block off or otherwise impede the flow of blood through the artery. Since the components of the closure device are all formed of resorbable materials, the closure device can be left in place within the body until it is absorbed.

As shown in Figures 13-17, an alternate embodiment of the present invention includes a modified tamping member 150, a locking disk 152 and temporary tamping member 154, all of which are preferably slidable distally along the positioning member 34. In this embodiment, the tamping member 150 may be formed of a variety of shapes such as a cylindrical, tubular or disk-shaped member and is preferably formed of a bioabsorbable material which is also preferably porous and may be similar to a moldable polyglycolic acid. In a preferred form of the present invention, the lengthwise dimension of the tamping member 150 is preferably significantly greater than the diameter of the tamping member. As with the embodiment described above, the tamping member 150 of the present embodiment preferably also includes a clotting agent mixed therein or coated thereon. As shown, the tamping member 150 preferably includes the positioning member 34 threaded therethrough so that the tamping member 150 is slidable along the positioning member into tamping contact with the sealing member 30 in the same manner as described above with respect to the preferred embodiment of the present invention. In this embodiment, the shorter length of the tamping member 150, as compared to the prior embodiment, creates an area in the puncture where the formation of a clot is promoted. This area is preferably well below the skin surface and is also above the wall of the blood vessel and plug so as to not interfere with the hemostasis action of the sealing member and anchor member while still preventing oozing or bleeding from the puncture immediately after the placement of the modified closure.

The locking disk 152 of this embodiment is preferably a bioabsorbable cylindrical member which may be formed of polymeric materials having rigidity characteristics similar to that of the anchor member 32. The locking disk 152 includes the filament member threaded therethrough so that the locking disk 152 may be pushed distally into the

puncture by a non-absorbable and removable temporary tamping member 154 which functions in the same manner as the tamping member 130 described above, except the temporary tamping member 154 is removed once the locking disk 152 is in the desired position in the puncture and need not be formed of a bioabsorbable material. The locking disk 152 is formed of a bioabsorbable material which preferably deforms once it is in contact with the fluids in the puncture and the warmth of the patient's body. This deformation allows the locking disk 152 to quickly contact and engage the positioning member to lock the tamping member 150, sealing member and anchor member in the desired position in the puncture distally of the locking disk 152 while maintaining tension along the positioning member between each of these bioabsorbable components.

In this embodiment, the tamping member 150 preferably includes a clotting agent which is significantly more effective than the sealing member 30 to promptly seal the puncture from any bleeding in the puncture or from any blood which may flow around the anchor member 32 and sealing member 30. This feature is possible with the tamping member 150 because the tamping member is spaced apart from the wall of the blood vessel; and, therefore, it cannot be inadvertently positioned in the blood vessel of the patient to promote clotting therein. The locking disk 152 eliminates the need for the spring 142 and the other components which are described above to initially maintain the tension on the positioning member once the tamping member 130 is used to tamp the plug in the puncture. In this embodiment, the user may cut the positioning member once the user confirms that the locking disk 152 has properly engaged the positioning member. Thereafter, the locking disk 152 will maintain the tension in the positioning member until the sealing member and anchor member cause the complete and final hemostasis in the

distal portion of the puncture adjacent to the wall of the blood vessel.

As should also be appreciated from the foregoing, the closure device, the instrument for deploying it and their method of use enables the ready, effective and efficient sealing of a percutaneous puncture in an artery. Thus, it is expected that the present hemostatic puncture closure device 20 will be a significant advancement in the fields of cardiology and radiology as well as other medical fields where the prompt and secure sealing of the punctures or incisions is desired. The present device may allow continuance of anticoagulation post-procedure, more aggressive use of thrombolytic agents and safer use of large bore catheters. It should also reduce discomfort and complication rates for patients, allow many in-patient procedures to be performed safely on an out-patient basis, decrease the time and cost of interventional procedures and reduce exposure of hospital personnel to human blood.

Without further elaboration, the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same or obvious equivalents for use under various conditions of service.

HEMOSTASIS PROMOTING DEVICE FOR SEALING A PUNCTURE IN A PATIENT

CLAIMS

What is claimed is:

1. An assembly for sealing an incision or puncture in the body of a patient wherein the puncture extends from the skin of the patient into a blood vessel, duct or lumen of the human patient, the assembly comprising;

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

a second member formed of a bioabsorbable material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member; and

a third member formed of a bioabsorbable material and positioned in the puncture proximally of said second member and having greater rigidity than said second member to seal the puncture from the flow of fluids therethrough.

2. The assembly of claim 1 wherein said second member is formed of a hemostasis promoting material which is absorbable within the body of the patient and said third member has greater clot promoting properties than said second member.

3. The assembly of claim 1 further including a filament member extending between said first and second members.

4. The assembly of claim 3 wherein said filament member is threaded through said second member and said filament member is frictionally engaged with at least one of said first member, second member or said third member.

5. The assembly of claim 3 wherein said filament member is at least initially slidable through said third member.

6. The assembly of claim 1 wherein said third member is formed of a material having sufficient rigidity to allow said third member to tamp said second member in the puncture.

7. The assembly of claim 1 wherein said third member at least partially encircles a filament member and said third member contacts said second member to tamp said second member into position adjacent to the blood vessel, duct or lumen of the patient.

8. The assembly of claim 1 wherein said first member is an anchor member.

9. The assembly of claim 1 wherein said second member is formed of a hemostasis promoting collagen material which is insertable into the puncture in the body of the patient.

10. The assembly of claim 1 wherein said first member is operatively positioned in the blood vessel of a patient and said second member is operatively positioned in the puncture and said third member extends in tamping contact with said second member such that said first member, said second member and said third member cooperatively seal the puncture from the flow of blood from the blood vessel therethrough.

11. The assembly of claim 10 wherein a filament member is in operative engagement with each of said first, second and third members to seal the puncture from the flow of fluids therethrough.

12. The assembly of claim 11 wherein said third member includes a clotting agent therein.

13. An assembly for sealing an puncture in the body of a human patient wherein the puncture extends from the skin of the patient into a blood vessel of the human patient, the assembly comprising;

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel of the patient;

a second member formed of a bioabsorbable and hemostasis promoting material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member; and

an elongate and tubular bioabsorbable member movable in the puncture to facilitate the insertion of at least one of said first member or said second member into the puncture to seal the puncture from the flow of fluids therethrough.

14. The assembly of claim 13 further including a filament member and wherein said tubular member is an elongate porous member and said tubular member is movable along said filament member into tamping contact with said second member in the puncture.

15. The assembly of claim 13 wherein said tubular member has greater columnar strength than said tubular member.

16. The assembly of claim 13 including an elongate introducer assembly having said first, second and third members therein and said first member is expelled from said assembly into the blood vessel of the patient and said second and third members are expelled from said assembly into the puncture.

17. An assembly for sealing a puncture in the body of a human patient wherein the puncture extends from the skin of the patient into a blood vessel, duct or lumen of the patient, the assembly comprising;

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

a second member formed of a bioabsorbable material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member;

a third member formed of a bioabsorbable material and positioned in the puncture proximally of said second member and having greater rigidity than said second member to seal the puncture from the flow of fluids therethrough; and

a locking member formed of a bioabsorbable material and positioned in the puncture to cooperatively retain said first and second members relative to each other in the puncture and seal the puncture from the flow of fluids therethrough.

18. The assembly of claim 17 further including a filament operatively interconnecting said first member and said second member and said locking member engaging said filament proximally of said second member.

19. An assembly for sealing an incision or puncture in the body of a patient wherein the puncture extends from the skin of the patient into a blood vessel, duct or lumen of the human patient, the assembly comprising;

a first member formed of a bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

a second member formed of a bioabsorbable material and said second member cooperatively seals the puncture from the flow of fluids therethrough in combination with said first member; and

a third member formed of a bioabsorbable material and positioned in the puncture proximally of said second member and having greater clot promoting properties than said second member to seal the puncture from the flow of fluids therethrough.

20. The assembly of claim 19 wherein said second member is formed of a hemostasis promoting material which is absorbable within the body of the patient and said third member has greater rigidity than said second member.

21. A method of sealing a puncture formed in the body of a patient wherein the puncture extends generally from the skin of a patient into a selected blood vessel of the patient, the method comprising;

inserting a first member into the puncture to a location generally adjacent to the wall of the blood vessel;

inserting a second member into the puncture such that the second member is positioned in the puncture proximally of the first member to seal the puncture from the flow of blood passing through the blood vessel;

inserting a third member into the puncture proximally of the second member

tamping the second member with the third member until hemostasis is achieved and then leaving the first, second and third members in the puncture to be absorbed by the body of the patient.

22. The method of claim 21 further including the step of ejecting first, second and third members into the puncture along a filament member.

23. The method of claim 21 further including the step of threading a filament member through the first, second and third members so that the filament member is frictionally engaged by the second and third members in the puncture.

24. The method of claim 21 further including the step of sliding a locking member distally into the puncture.

25. The method of claim 21 further including sliding the locking disk distally along the filament member into locking engagement therewith.

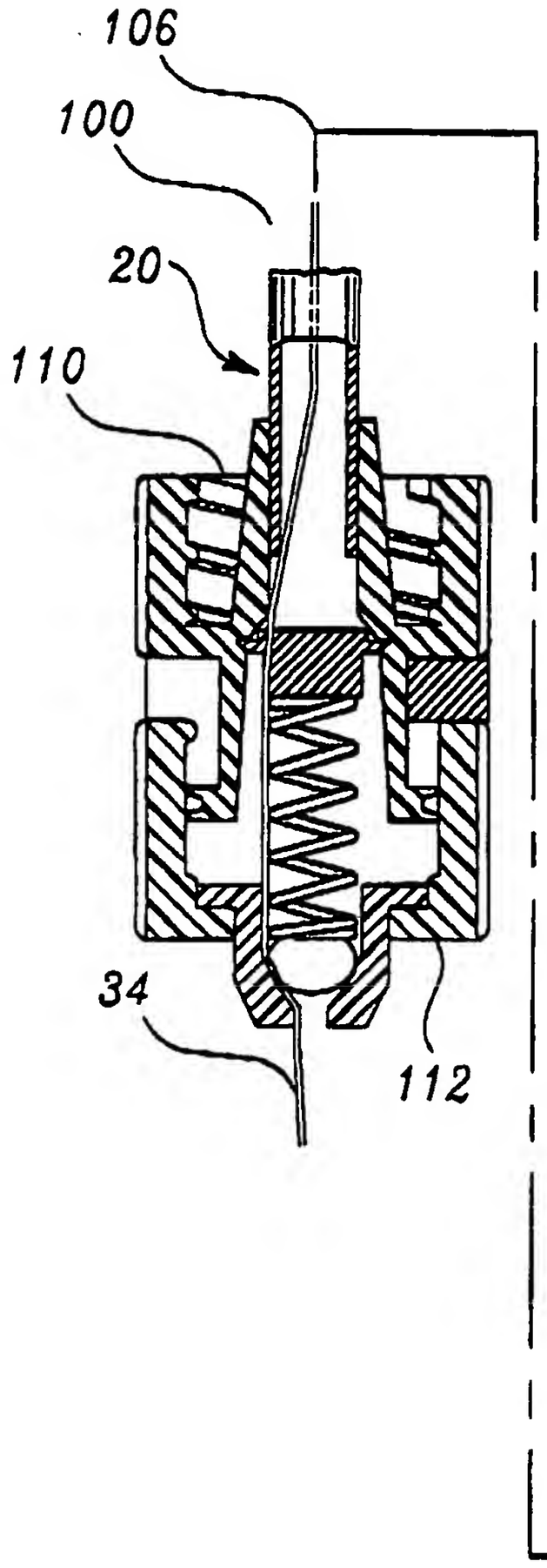


figure 1

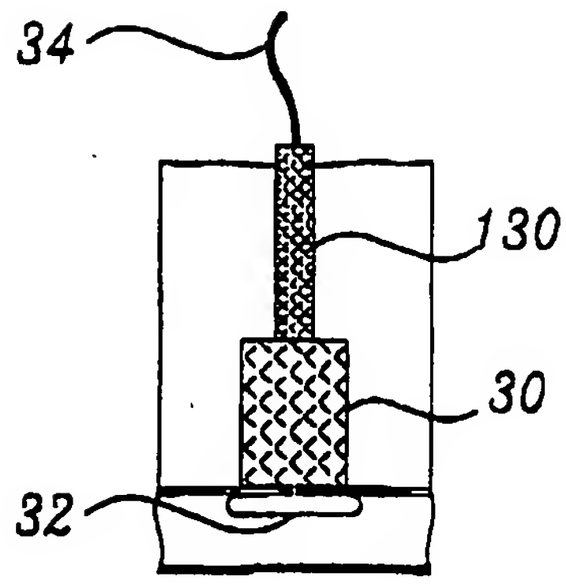


figure 2

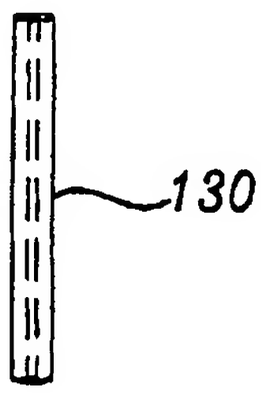


figure 3

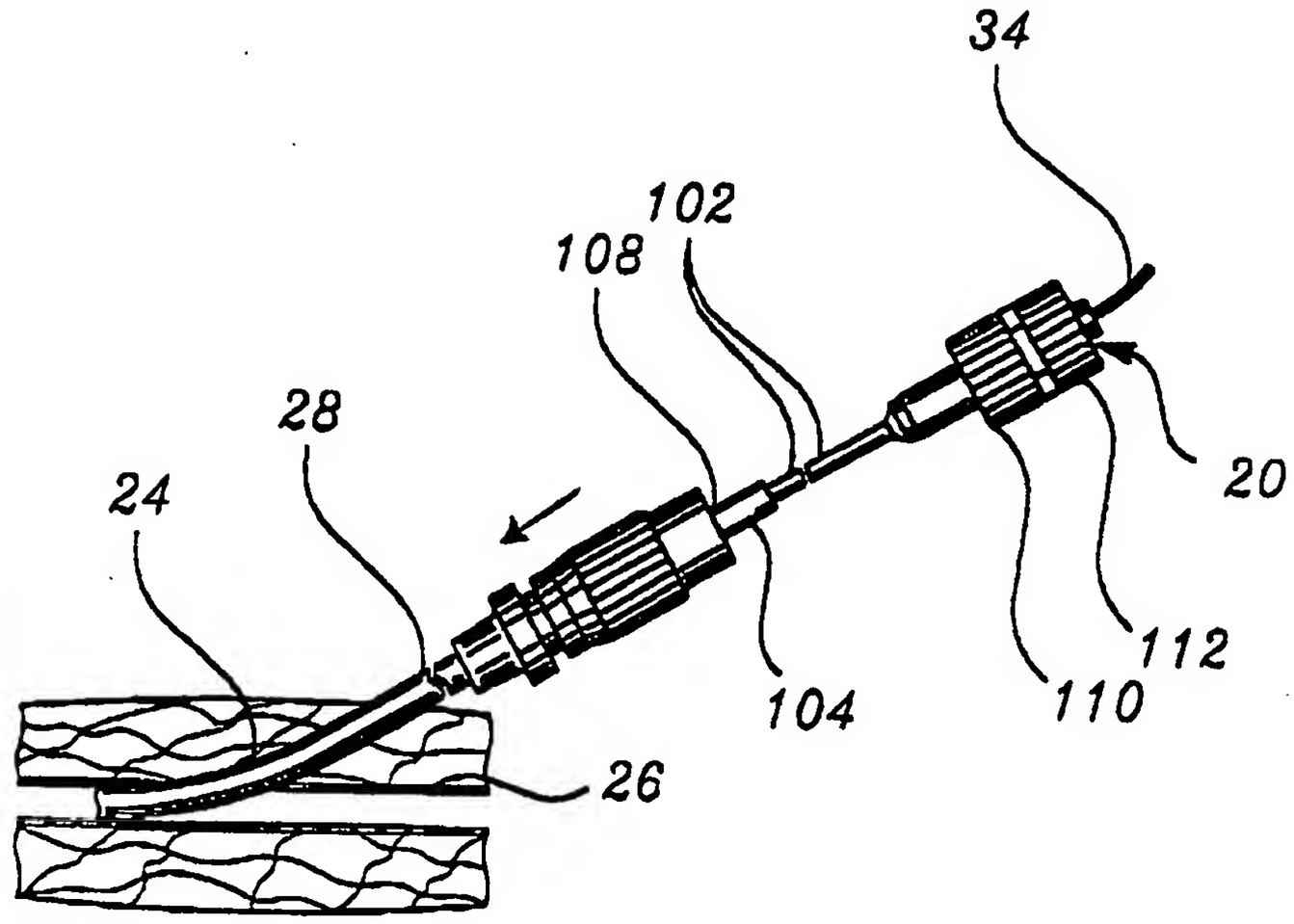
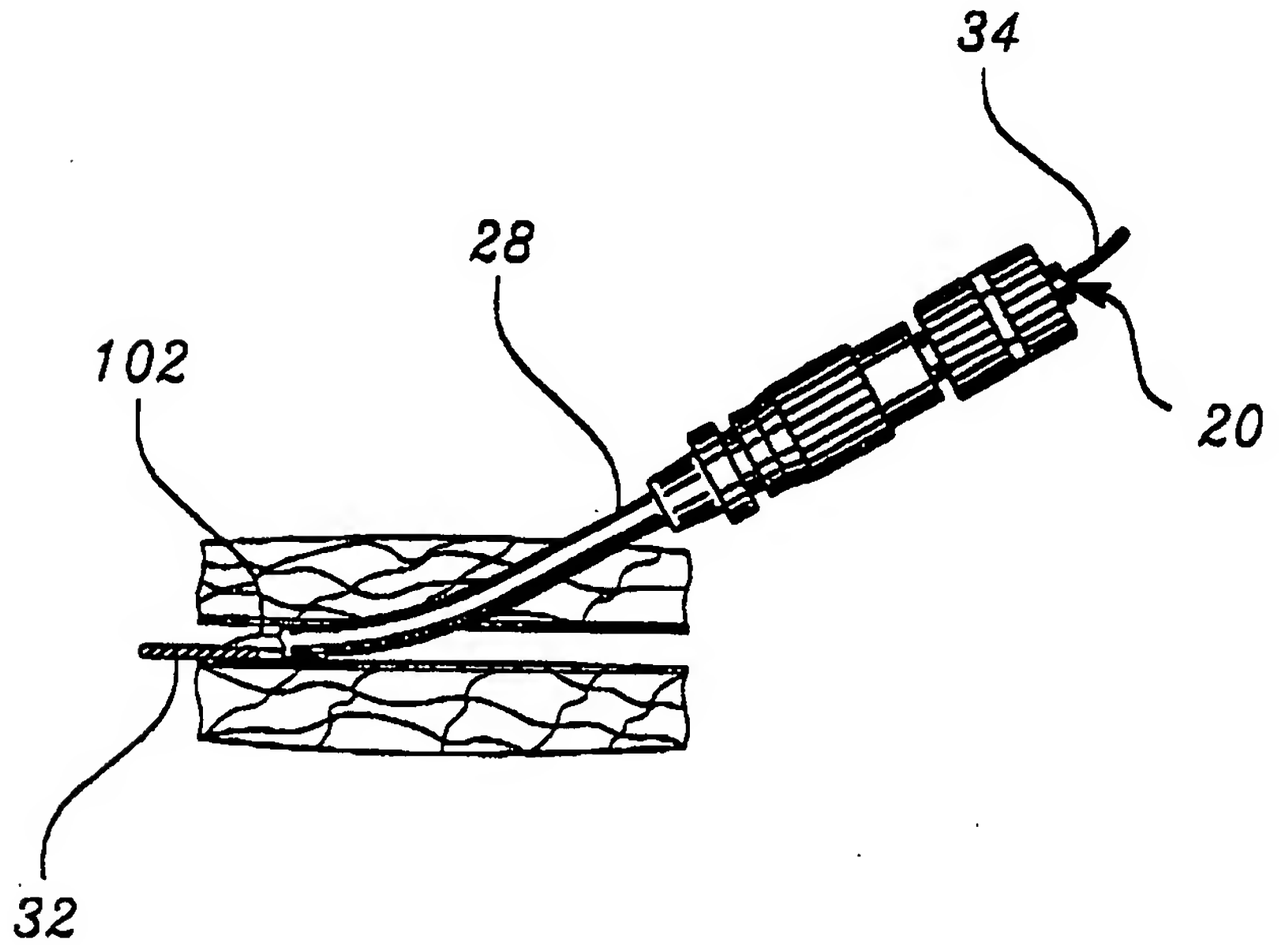


figure 4



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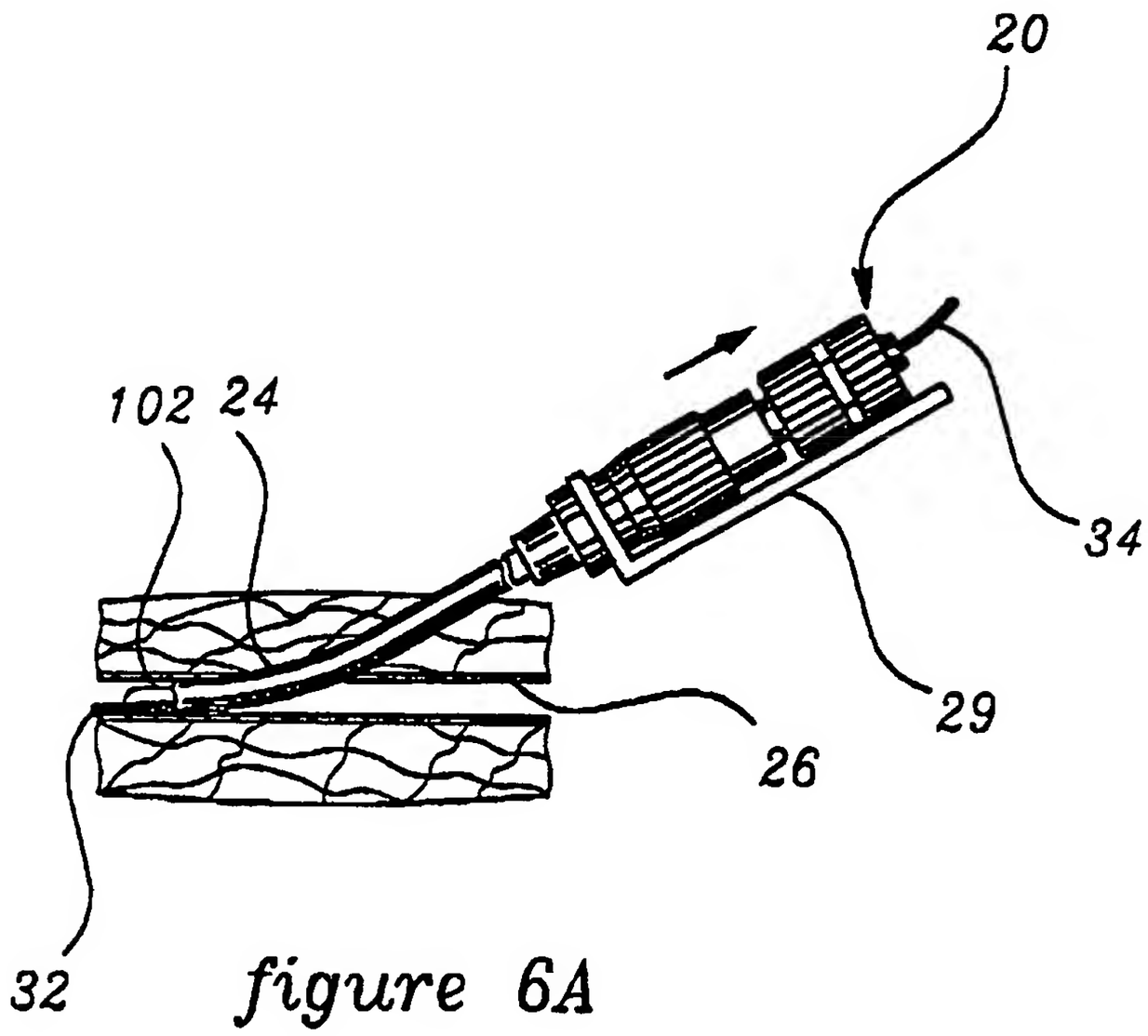

figure 6A

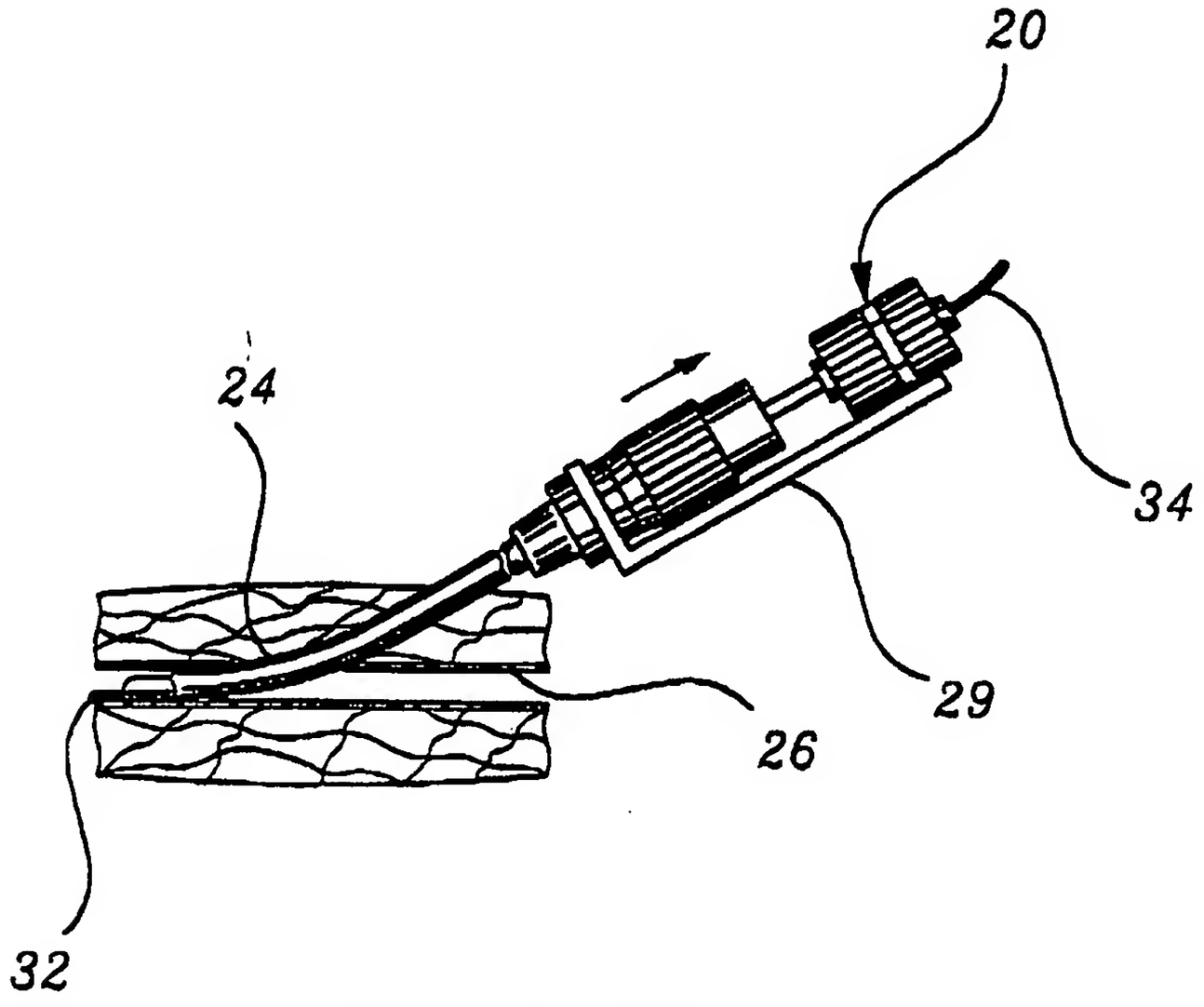

figure 6B

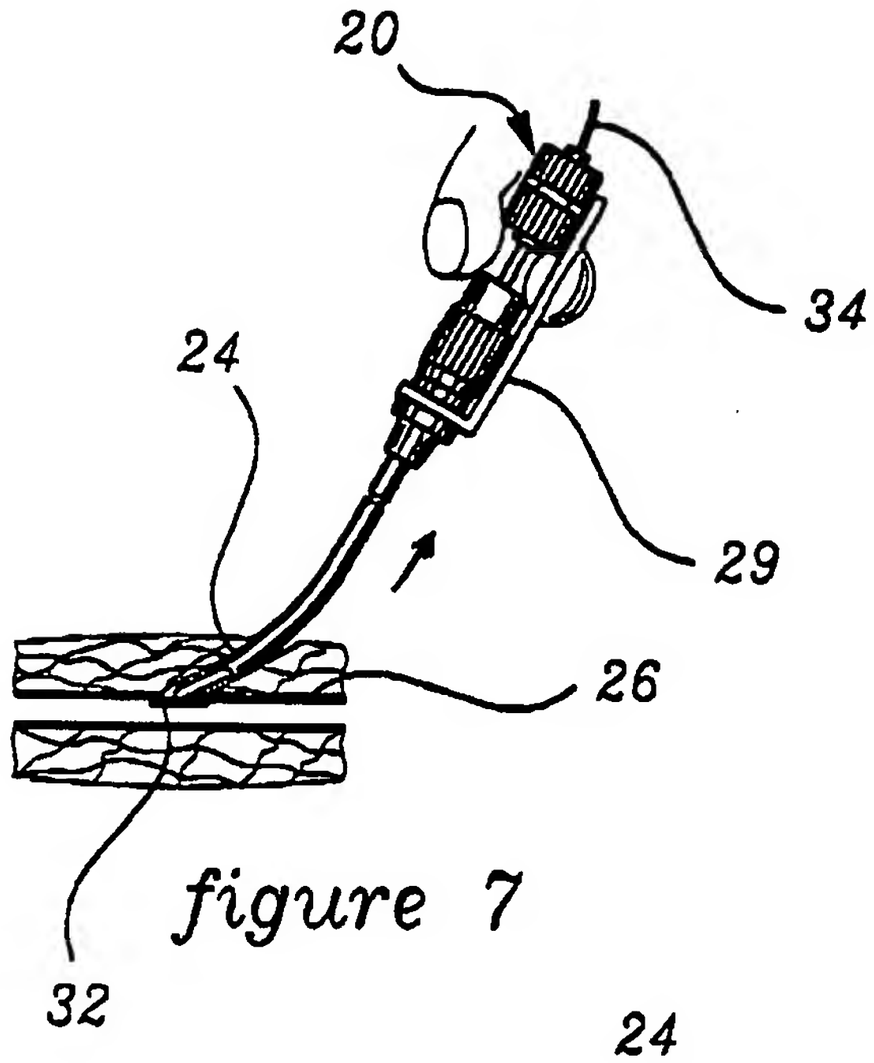

figure 7

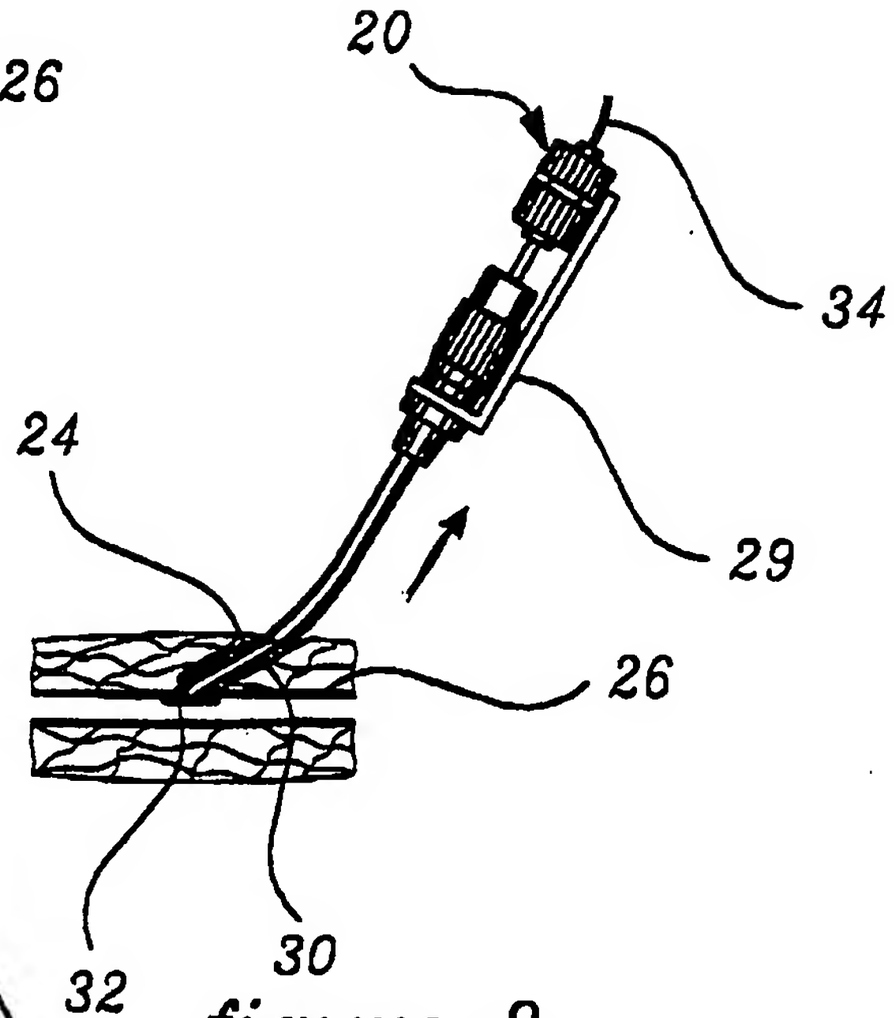

figure 8

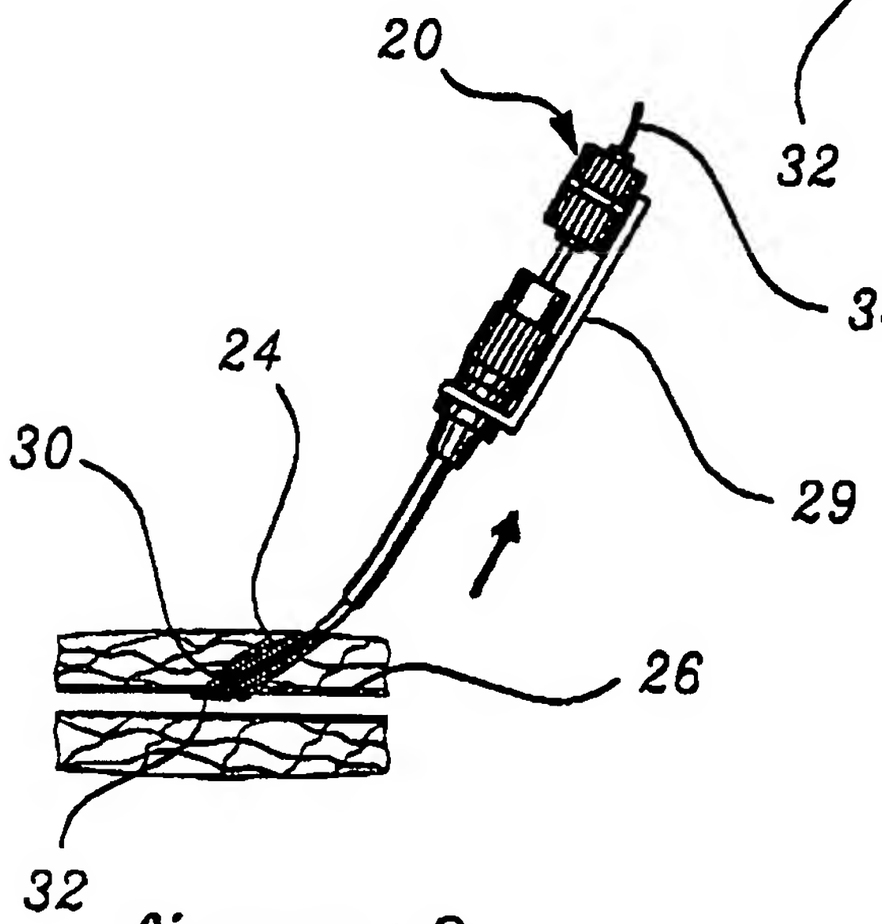

figure 9

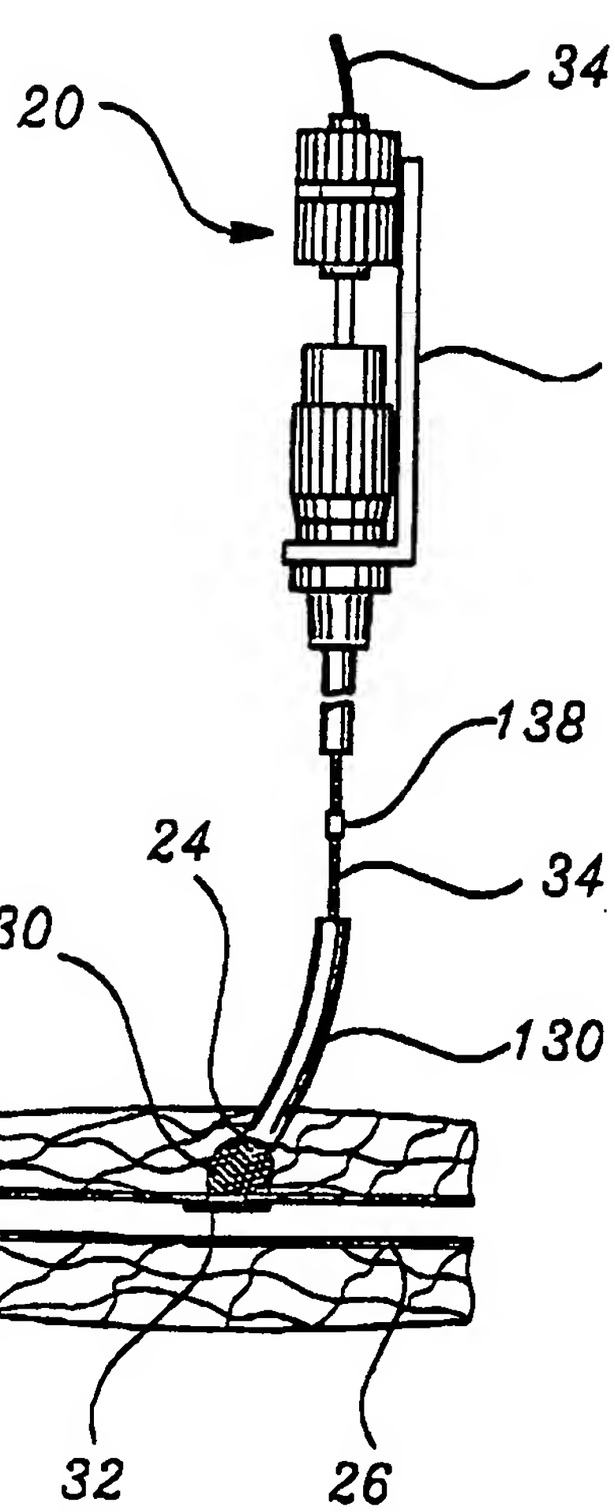

figure 10

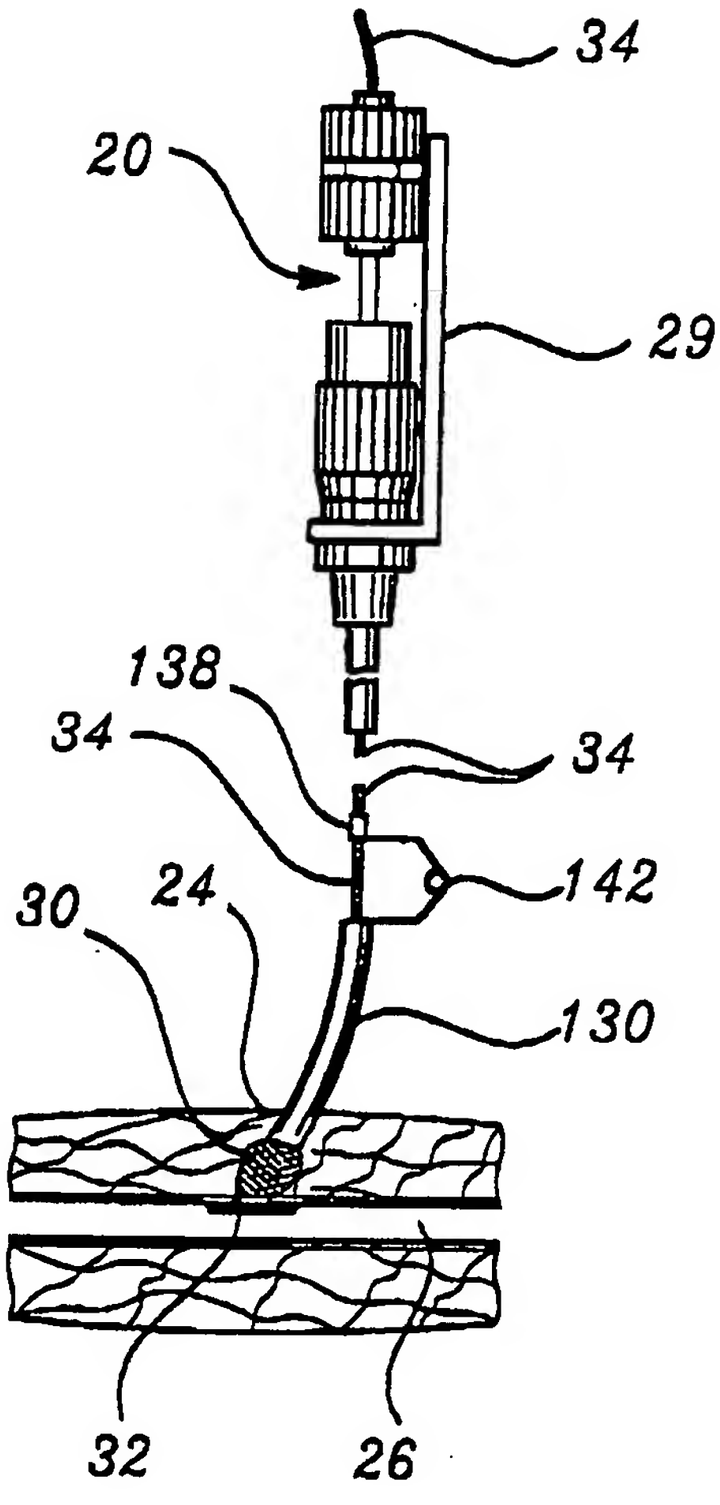

figure 11

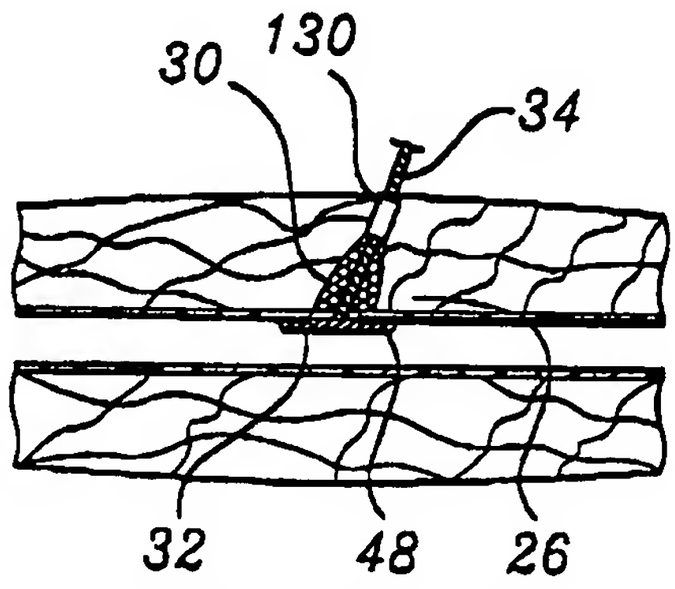

figure 12

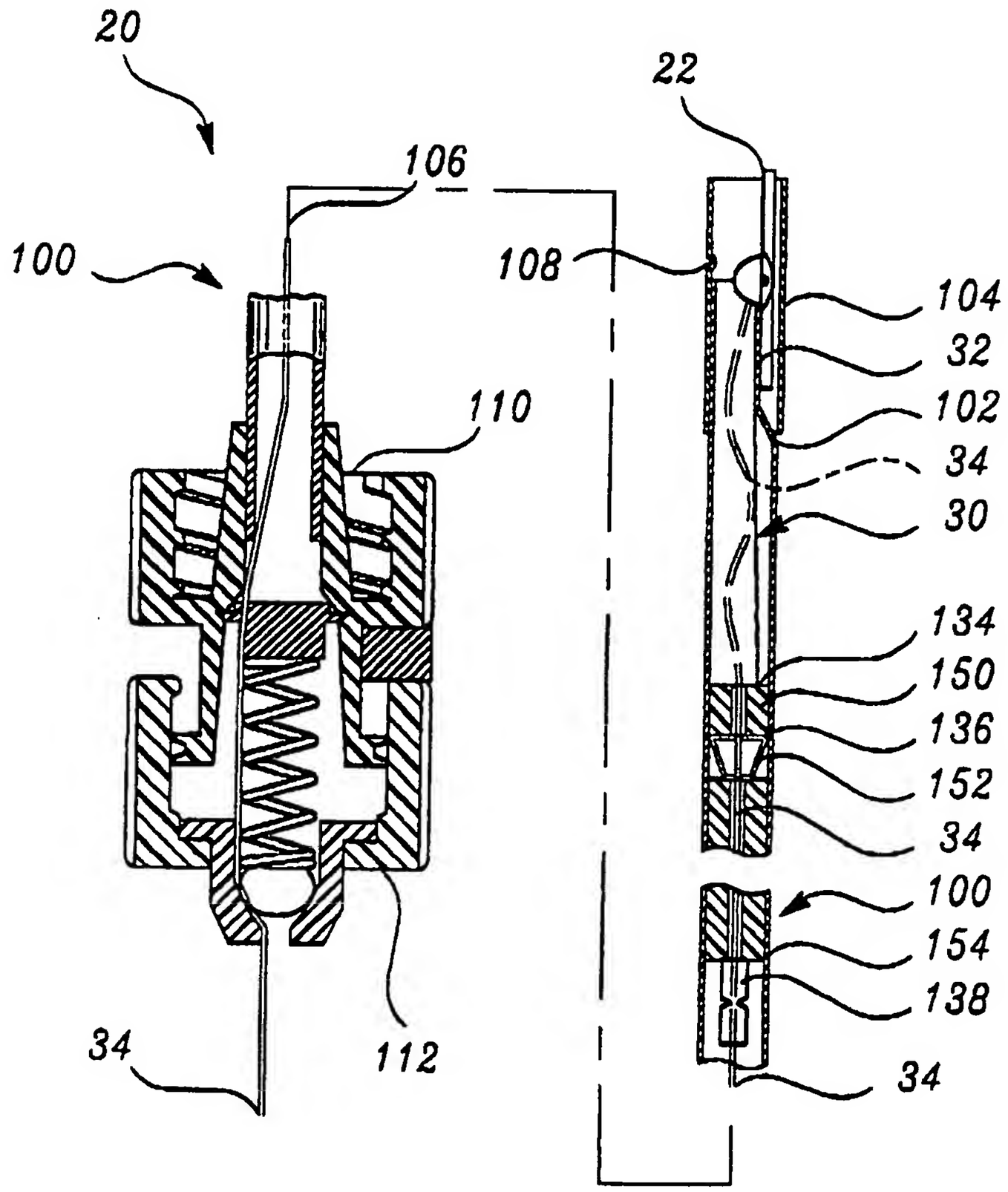
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figure 13

figure 17

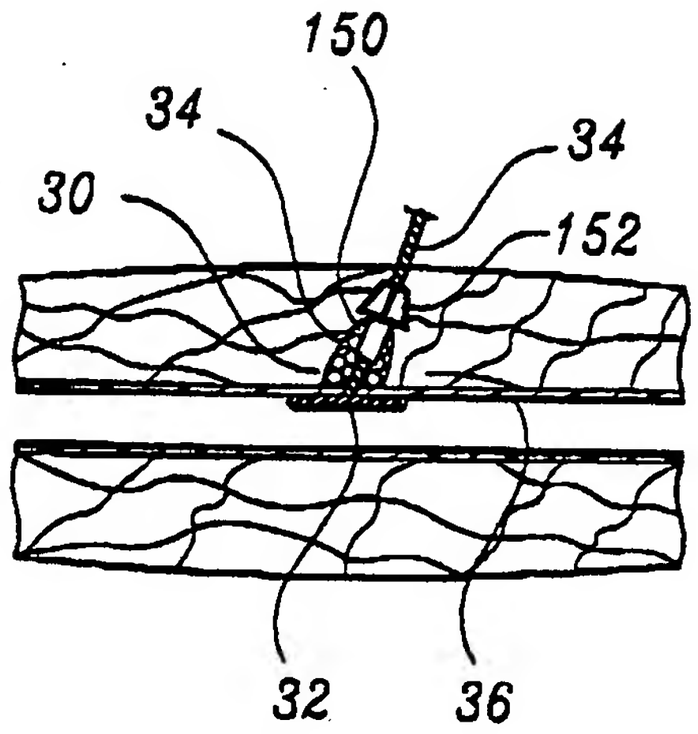

figure 15

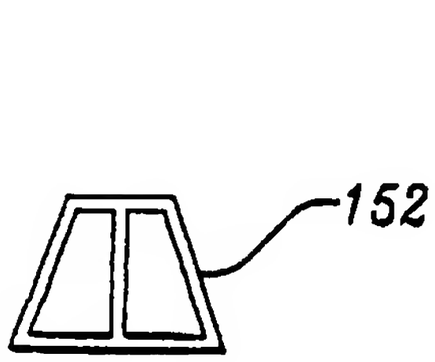

figure 16

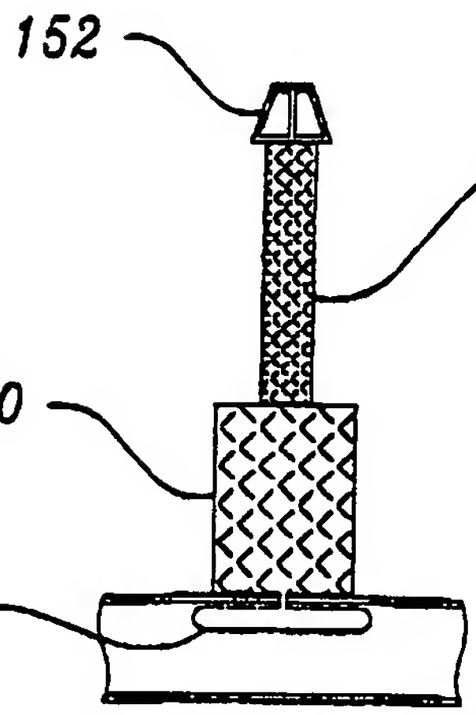

figure 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01102

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04
US CL :606/213

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/15, 60; 606/139, 213, 215

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,370,660 A (WEINSTEIN et al) 06 December 1994, col. 4 lines 33-64.	1-25
A	US 5,441,517 A (KENSEY et al) 15 August 1995, col. 2 lines 17-50.	1-23
A	US 5,545,178 A (KENSEY et al) 19 August 1996, col. 5 lines 26-52.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
15 APRIL 1998	23 JUN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GARY JACKSON Telephone No. (703) 308-4302

Form PCT/ISA/210 (second sheet)(July 1992)★